

Certificate

mdc medical device certification GmbH
certifies that

Elcam Medical ACAL
Baram 1386000
Israel

for the scope

**Development, design, manufacturing and sales of
disposable medical devices for fluids administration, withdrawal,
transfusion and pressure monitoring, and of disposable & reusable auto-injectors**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

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| Valid from | 2023-07-05 |
| Valid until | 2026-07-04 |
| Registration no. | D2001100014 |
| Report no. | P22-01802-254239 |
| Stuttgart | 2023-07-05 |



Head of Certification Body

